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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/647,279 | 07/18/2001 | Kazumi Iijima | K0208-013 | 5027 |

23723 7590 09/25/2002

Patterson Belknap Webb & Tyler, LLP
Attention: I.P. Docketing
1133 Avenue of the Americas
New York, NY 10036

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| EXAMINER |
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AUGHENBAUGH, WALTER

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1772

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 09/647,279 | Applicant(s) IIJIMA, KAZUMI | |
| | Examiner Walter B Aughenbaugh | Art Unit 1772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a plastic syringe barrel.

Group II, claim(s) 6, drawn to a method for improving a plastic syringe barrel.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group II has a special technical feature directed to the enhancement of the connection strength of the luer lock portion that is not required for Group I.

3. During a telephone conversation with Neal Feivelson on September 4, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5.

Affirmation of this election must be made by applicant in replying to this Office action. Claim 6 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, the structure is vague and indefinite. The structure intended to be recited by the phrases “a plastic syringe barrel”, “nozzle portion of the plastic syringe barrel” and “a luer lock portion composed of a cylindrical space”. Is the “luer lock portion” only the “cylindrical space” or do the inner and outer cylinders comprise the “luer lock portion”? The claim should positively set forth the purpose of the plastic syringe barrel and the nozzle portion and the structure necessary for carrying out the purpose, i.e., the claim is incomplete in regard to the structure of the plastic syringe barrel and the nozzle portion. No structure is claimed for the plastic syringe barrel or the nozzle portion; therefore, the scope of the claim cannot be ascertained. The language of the claims should be limited to the invention, which seems to be the “luer lock portion”.

In further regard to claim 1, the phrase “wherein all or part of an inner surface of said luer lock portion is subjected to surface roughening treatment” is a process limitation. The method of forming the roughened surface of the luer lock portion is not germane to the issue of patentability of the luer lock portion itself. Therefore, this limitation has not been given patentable weight. No structure is positively recited in the phrase quoted in this paragraph.

In regard to claim 2, this claim recites a process limitation that has not been given patentable weight.

In regard to claim 3, the phrase “is formed” is indefinite. The screw thread structure needs to be positively recited. The use of “and/or” is indefinite because the scope of the claim

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cannot be ascertained. The claim is incomplete in regard to the structure of the "screw root portion". The limitation "is subjected to surface roughening treatment" is a process limitation that has not been given patentable weight.

Claim 5 recites a process limitation that has not been given patentable weight. There is no structure recited in this claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Moncada et al.

In regard to claim 1, Moncada et al. teach a male Luer lock connector portion 24 with cylindrical portion 30 which corresponds with the inner cylinder of claim 1 (col. 4, lines 2-4 and Figure 1). Moncada et al. also teach a cylindrical portion 30 has ears 34 for securing the Luer lock portion 24 into a cooperating Luer lock portion (col. 4, lines 4-6 and Figure 1). Moncada et al. also teach that the outside surfaces of the ears 34 include teeth 48, and that teeth 48 or any other type of roughened surface are formed on the rear surface 50 of ears 34 (col. 4, lines 42-60 and Figures 1 and 2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

Moncada et al. teach the syringe connector structure as discussed above. Moncada et al. fail to explicitly teach that the inner peripheral surface of the outer cylinder is subjected to roughening treatment. However, since Moncada et al. teach that the outside surfaces and rear surface 50 of ears 34 have teeth or any other type of roughened surface for increased frictional engagement between ears 34 and a cooperating female Luer lock portion (col. 4, lines 42-53), one of ordinary skill in the art would have recognized to form teeth or any other type of roughened surface on the inner peripheral surface of the outer cylinder of the Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed teeth or any other type of roughened surface on the inner peripheral surface of the outer cylinder of the Moncada et al. for increased frictional engagement between ears 34 and a cooperating female Luer lock portion as taught by Moncada et al.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

Moncada et al. teach the syringe connector structure as discussed above. Moncada et al. Also teach a Luer lock connector 118 with ears 122 on the male Luer lock portion of the needle

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mount and threads 124 on female Luer lock portion 118 (col. 6, lines 7-16). Moncada et al. fail to explicitly teach that the threads 124 have a roughened surface. However, since Moncada et al. teach that the outside surfaces and rear surface 50 of ears 34 have teeth or any other type of roughened surface for increased frictional engagement between ears 34 and a cooperating female Luer lock portion (col. 4, lines 42-53), one of ordinary skill in the art would have recognized to form teeth or any other type of roughened surface on the threads 124 on female Luer lock portion 118 of Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed teeth or any other type of roughened surface on the threads 124 on female Luer lock portion 118 of Moncada et al. for increased frictional engagement between ears 122 and female Luer lock portion 118 as taught by Moncada et al.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Porfano et al.

Moncada et al. teach the syringe connector structure as discussed above. Moncada et al. fail to teach that the material of the connector structure is cyclic polyolefin resin. Porfano et al., however, teach a syringe barrel 12 that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe connector structure of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic polyolefin copolymer resin as the material of the syringe connector structure of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Lampkin.

Note, however, that this claim is not given patentable weight since "wherein said surface roughening treatment is blast treatment" is a process limitation; no structure is positively recited in this claim.

Moncada et al. teach the syringe connector structure as discussed above. Moncada et al. fail to explicitly teach that the surfaces of the syringe connector structure are roughened via blast treatment. Lampkin, however, discloses a syringe 10 with tubular barrel 11 constructed of thermoplastic material (col. 2, lines 32-36). Lampkin discloses that a surface of the syringe is roughened by sand blasting or other roughening processes. One of ordinary skill in the art would recognize to roughen surfaces of the syringe connector structure of Moncada et al. via blasting since blasting is a notoriously well known roughening process as taught by Lampkin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have to roughened surfaces of the syringe connector structure of Moncada et al. via blasting since blasting is a notoriously well known roughening process as taught by Lampkin.

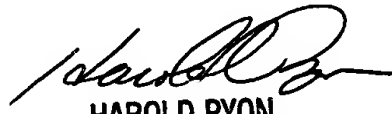
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Aughenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
09/24/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
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